REMARKS

The specification has been amended to include material incorporated by reference in the specification. Claim 12 has been amended to delete recitation of the use of the inventive compositions for the treatment of a gastrointestinal condition. Claim 20 is added to reflect particular forms of a composition that can retain crystalline structure as supported by paragraphs [0040], [0045] and [0046].

The September 7, 2004 Office Action maintains the rejection of claims 1-19 under 35 U.S.C. 112, first paragraph, but now alleges that the subject matter was not described in such a way to enable one skilled in the art to make and use the invention.

As understood in light of the November 20, 2003 Office Action, Applicants believe that the Office Action asserts that the claimed use of the inventive compositions is not supported. More specifically, the Office Action states (1) that "When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that use" (citing MPEP 2164.01(c)); (2) that setting forth uses of olanzapine by incorporating by reference the references referred to in paragraphs 30-33 is improper, and (3) the absence of working examples is evidence of nonenablement. Applicants respectfully traverse.

First, Applicants note that claims 1-11 are not limited by use. Therefore, enablement of those claims does not require evaluation based upon any particular use, but upon the claim itself. To require evaluation of use would improperly import limitations from the specification or from other claims into claims 1-11. Thus, claims 1-11 are fully enabled and allowable.

Second, Applicants submit that the material contained in the cited references is not essential, but is present in order to show the state of the art. The incorporation by reference is thus proper. As demonstrated by the references, persons skilled in the art would be readily aware of the use of olanzapine in the treatment of a psychotic condition, schizophrenia and schizophreniform disorders, acute mania, Bipolar I Disorder, psychotic mood disorder and psychosis associated with Alzheimer's disease. Thus, a pharmaceutical composition comprising olanzapine and its use as claimed in claims 12-19 is fully supported by the specification as filed. Information known to persons skilled in the art need not be present in the specification. Accordingly, claims 1-19 are in condition for allowance.

Third, the presence of one or more working examples is not required for enablement. (See MPEP 2164.02) As stated in the MPEP, lack of a working example is a factor to consider in a case involving an unpredictable and undeveloped art. Claims 1-11 involve a pharmaceutical composition comprising an active ingredient and one or more pharmaceutically acceptable carriers, excipients or diluents. Claims 12-19 are drawn to uses of the novel olanzapine polymorph described in the specification for treatment of disorders that olanzapine is known to treat. Neither of these claims involve art that is sufficiently "unpredictable and undeveloped" to require the presence of a working example. Accordingly, claims 1-19 are fully enabled by the specification.

Notwithstanding the above Applicants have amended the specification to incorporate material from the references which is believed to be sufficient to overcome the rejections set forth in the Office Action. Undersigned counsel submits that the amendatory material consists of the same material incorporated by reference and already of record in the application, having been submitted in an Information Disclosure Statement at the time of filing the application. Applicants reserve the right to further amend the specification as required to overcome any subsequent rejections.

The September 7, 2004 Office Action also rejects claims 1-11 under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 5,229,382 to Chakrabarti. Applicants respectfully traverse.

It is axiomatic that, in order to anticipate a claim, a reference must contain, either expressly or inherently, each and every limitation of the claim. There is simply nothing in Chakrabarti that discloses the olanzapine polymorphs having x-ray diffraction patterns and infrared spectra described and claimed in the present application.

Furthermore, it is possible to have liquid pharmaceutical compositions that retain the crystalline form of a compound. For example, when the formulation is in form of suspension, it is possible for drug to retain is crystalline form. Further a gel can be in the form of suspension or as a solution. If the gel is in the form of suspension it is possible to retain the crystalline nature of the drug. Hence in general it is possible to formulate a liquid formulation containing polymorphs provided the liquid formulation is not in the form of solution.

For at least these reasons, Chakrabarti can not anticipate the claimed invention and the rejection of claims 1-11 under 35 U.S.C. 102(b) should be withdrawn.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner indicate the allowability of claims 1-20 and the application pass to issue. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment is respectfully requested.

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Respectfully submitted,

By _____

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